MAR - 1 2000

K000011

SECTION 2.0 – SUMMARY AND CERTIFICATION

2.1 General Information

2.1.1 Company Name, Address, and Telephone Number

Lake Region Manufacturing, Inc. (LRM)
340 Lake Hazeltine Drive
Chaska, MN 55318
Telephone: (612) 448-5111 Fax: (612) 448-3441

2.1.2 Device Trade Name/Proprietary Name

LRM produces guidewires on an OEM basis for other manufacturers, kit assemblers, and distributors. Consequently there are a large number of trade and proprietary names not including or associated with LRM. LRM has no proprietary names of its own to be included with this submission.

2.1.3 Device Common Names/Usual Names and Classification Names

These devices are commonly known as guides, guidewires, or spring guidewires. The current classification names, and product codes are Angiographic Guidewire (74HAP), Catheter Guidewire (74DQX), and Radiological Catheter Guidewire (74JAJ).

2.1.4 Establishment Registration Number: 2126666

2.1.5 Classification of Devices

The classification names listed above were originally classified as Class II devices by the Neurology (84HAD), Cardiovascular (74DQX) and Radiology (90JAJ) Review Panels, respectively.

2.1.6 Applicability of Performance Standards

LRM has determined that no mandatory performance standards have been established for these devices under Section 514 of the Medical Amendments to Federal Food, Drug, and Cosmetic Act or by any subsequent regulatory action. LRM has also determined that there are no applicable voluntary standards.

2.2 Labels, Labeling, and Advertising

LRM produces cardiovascular and vascular guidewires on an OEM basis for other manufacturers, kit assemblers, and distributors. There is no direct distribution by LRM. Changes to the customer controlled labels, labeling, or promotional material are at their discretion, including the resolution of any resulting regulatory obligations. A fraction of the total production bears LRM controlled labels and labeling.

2.3 Summary of Safety and Effectiveness

This summary is being included in the Premarket Notification submission in lieu of a statement of availability.

2.4 Device Description

2.4.1 Nickel Titanium steerable core with a colored (black) radiopaque jacket, with a polymer/hydrophilic coating applied over the core/jacket. The guidewires are bound by the following parameters:

Outside Diameter:	.018" - .038"
Lengths:	150 cm – 260 cm
Tips:	Straight or shaped with standard or long taper tip flexibility

NOTE: None of these guidewires are for PTCA use.

2.4.2 Engineering Specifications

The design specifications are the same for the proposed device as they are for the LRM predicate device [reference 510(k) K981326]. The finished devices must meet the same design criteria. Section 2.5 contains comparative data to demonstrate equivalency.

2.5 Substantial Equivalence Data

2.5.1 Background Information

The table below lists the differences between the predicate device and the proposed device. Testing was done to ensure the changes to the device met the predetermined acceptance criteria.

Item	**Proposed Device Differences from LRM Predicate cleared under 510(k) K981326**
Raw Materials	Steerable core: No changes to raw material **Radiopaque jacket:** **Change from pebax with bismuth for radiopacity** **To** **Polyurethane with tungsten for radiopacity** Polymer/Hydrophilic coating: No change to raw material
Assembly Process	No change to assembly processes
Physical Characteristics	No change except in color from clear or custom color to black
Labeling/IFU	No change to labeling or IFU
Intended Use	No change to intended use
Anatomical Sites	No change
Target Population	No change

Performance Testing	No change except for increased radiopacity
Safety Characteristics	No change
Biocompatibility	No change
Risk Analysis	No change

In order to demonstrate equivalence of the proposed device, LRM performed comparative testing between these guidewires manufactured with the modified jacket and the currently marketed LRM hydrophilic guidewires. LRM chose a product mix of four groups of wires, based on the LRM currently marketed hydrophilic guidewire line of standard configurations, including straight and shaped distal tips. LRM samples were produced following current manufacturing processes and procedures. All samples were sterilized prior to testing.

2.5.2 Comparative Test Data

Within each of the four groups, production samples were made from the most appropriate size guidewires. For each test series, samples were produced per standard manufacturing procedures. For each test type, either fifteen (15) or ten (10) test samples were selected. Some of the tests are destructive in nature, which required the selection of additional sets of fifteen (15) or ten (10) samples to perform other tests.

The following product qualification tests were performed:

2.5.2.1 Visual: Assess the product for visual appearance, such as tip integrity and jacket durability (cuts, splits, seams, etc., any indication that the tip has been compromised).

2.5.2.2 Dimensional Measurement – Outside Diameter, Dry and after 10 minute soak and after 40 minute soak in normal saline: Laser micrometer measurement of the outside diameter of the guidewire at multiple body points.

2.5.2.3 Lubricity: Measures the force required to insert and withdraw the guidewire within a catheter lumen standardized to each guidewire diameter.

2.5.2.4 Pull Test: Measures the strength of materials and joints in the guidewire.

2.5.2.5 3-Point Bending Test: Assess guidewire body stiffness/flexibility.

2.5.2.6 Coating Durability: Measures the lubricity before and after multiple catheter insertions and withdrawals.

2.5.2.7 Distal Tip (J) Memory: Assess the memory of the distal tip form of shaped product.

2.5.2.8 Linear Stiffness: Measures the linear tip flexibility.

2.5.2.9 Torque Control: Assess the guidewire torque response and rotational control to allow placement of the distal tip at a desired location in a 360 degree circle when controlled from the proximal end of the guidewire. Cotnrol may be clockwise or counter-clockwise.

2.5.2.10 Torque Fatigue: Assess the torqueable strength of a guidewire.

2.5.2.11 Radiopacity: Measures the radiopaque ability of the guidewire.

2.5.2.12 Jacket Durability: Measures the durability of the modified jacket material.

RESULTS: ALL TEST RESULTS WERE WITHIN PRESCRIBED SPECIFICATION LIMITS.

2.6 Qualification and Biocompatibility Test Data

2.6.1 Design Control

LRM is in conformance with the design control procedure requirements as specified in 21 CFR 820.30. Risk analysis was completed by means of a Failure Mode and Effect Analysis (FMEA) and all verification and validation activities resulted in the ability to demonstrate that the predetermined acceptance criteria were met.

2.6.2 Material/Product/Process Qualification

LRM has formal quality systems in place to assure that each product manufactured with the modified jacket material remain equivalent to the predicate products, and that the changes will not have an adverse affect on the safe and effective use of the product. The quality systems include Engineering Change Order Review, Material Qualification, Product Qualification, and Process Qualification. These controls are applied to each product size/group.

2.6.3 Biocompatibility Testing

LRM has adapted the biocompatibility testing recommendations in the FDA's General Program Memorandum #G95-1 Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing", dated May 1, 1995.

The following table lists the tests that were performed and the test results.

TEST PERFORMED	TEST RESULTS
Acute Systemic Toxicity	No signs or symptoms of Systemic Toxicity were observed for any of the samples.
Cytotoxicity (MEM)	Pass – Grade 1
Hemolysis	The samples did not produce hemolysis.
Intracutaneous Test	For all samples, skin reactions were not significant.
Pyrogen (Material Mediated)	The samples did not produce a pyrogenic response.
Inhibition and Enhancement	No endotoxin detected at 0.03 eu/ml.
Sensitization	The samples were deemed to be a weak sensitizer.
Physicochemical	The samples passed.

2.7 Packaging and Sterilization Information

LRM produces guidewires on an OEM basis for other manufacturers, kit assemblers, and distributors. There is no direct distribution by LRM. A portion of the production is private label, sterile packaged to customer specifications, a fraction of that product is provided sterile to the customer.

The single packaged modified jacket polymer/hydrophilic coated guidewires are placed in a dispenser and then into a Tyvek/poly pouch, along with a tray containing a torque device. The product may be packaged as five (5) pouches in a shelf carton five (5) pack, which is a typical packaging configuration.

There will be no changes to the sterilization process for the portion of packaged product shipped sterile to the customer. For the product that is shipped bulk, the packaging design and sterilization process parameters are the customer's responsibility. LRM will not recommend that its customers modify their packaging or sterilization procedures as a result of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 2000

Mr. Jim Klosterman
Lake Region Manufacturing, Inc.
340 Lake Hazeltine Drive
Chaska, MN 55318-1029

Re: K000011
Hydrophilic Coated Guidewire
Regulatory Class: II (two)
Product Code: 74 DQX
Dated: January 31, 2000
Received: February 2, 2000

Dear Mr. Klosterman:

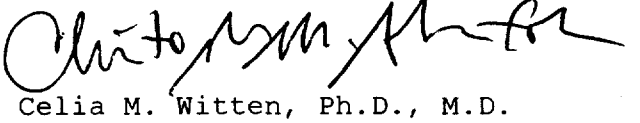
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Unknown

Device Name: Hydrophilic Coated Guidewire

Indications for Use:

To facilitate the placement of devices for diagnostic and interventional procedures.

NOTE: These guidewires are not intended for PTCA use.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Witten

Division Sign-Off
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K000011

Prescription Use __X__ Or Over-The-Counter Use _____
(PER 21 CFR 801.109)